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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,267

06/17/2008

Lawrence Solomon

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,267	<b>Applicant(s)</b> SOLOMON ET AL.	
	<b>Examiner</b> Lakshmi S. Channavajjala	<b>Art Unit</b> 1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-18-07</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Receipt of IDS dated 5-18-07 is acknowledged.

Claims 1-19 are pending in the instant application.

#### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,318,935; claims 1-20 of US patent No. 7329418; claims 1-8 of US patent No. 7622137; claims 1-27 of US patent no. 7713547; and claims 1-8, 12, 15 ad 19-20 of US patent No. 7838031.

Alternatively, instant claims unpatentable over any one of the following: claims 1-11 of U.S. Patent No. 7,318,935; claims 1-20 of US patent No. 7329418; claims 1-8 of US patent No. 7622137; claims 1-27 of US patent no. 7713547; and claims 1-8, 12, 15 ad 19-20 of US patent No. 7838031, and further in view of US 6375956 to Hermelin et al.

2. Although the conflicting claims are not identical, they are not patentably distinct from each other.

3. Instant claims are generally directed to a tablet comprising top and a bottom segment and with a separation mark such as a score or an indicia on one side of the tablet, wherein the score or separation is present in an intermediate/inner segment that has either the same drug as that of the first segment or no drug when the first segment has no drug and has a different color from the first segment. Further instant claims are directed to a method of breaking the above tablet at a separation mark.

4. Patent 7838031 claims

The invention claimed is:

- 5     1. A method of providing a partial dose of a drug or drugs contained in a layered tablet, said method comprising:
  - a) providing a bi-layer tablet comprising two or more seg-  
ments wherein a first layer is scored, forming one or  
more segments comprising a composition containing a  
10     drug or drugs, and a second layer forming a segment comprising an inactive or drug-free composition, said second inactive layer or segment providing structural integrity to, and accurate tablet breaking for, the scored tablet;
  - 15     b) dividing said tablet through said first and second segments to create a tablette comprising the partial dose; and
  - c) administering to a patient in need of treatment said  
5.     tablette containing the partial dose of the drug or drugs.

6.     The above patent further claims that the score traverses through a first segment and the tablet is an immediate release dosage form. Instant patent also claims a layered tablet wherein a separation mark is placed in the inner segment. However, the inner segment can also be a part of the first segment because the two (1st and inner) segments can have the same or no drug. Accordingly, a score present in the inner layer when the first and inner layers are made of the same drug or no drug then the score would have been present in the first segment. While above claims are silent regarding the horizontal score, the figure 1 of the patent shows that the score is horizontal and accordingly, the burden is on the applicants to show that the patented claims do not require a vertical score. Hence, the patented claims anticipate instant claims.

7.     7318935 patent claims a layered tablet for immediate release of drug comprising a top, bottom and a middle layer wherein the middle layer is free of drug and further

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having a horizontal score or printed indicia. The drugs present in the first and second segments are compatible but may be same or different. While '935 patents do not state that the inner segment is of a different color than the first and second segments, it would have been obvious for a skilled artisan at the time of the instant invention was made to employ different colored segments in the tablet of '935 patent such that the different segments are easily identified and the breaking of the tablet through the score present in a middle colored segment would have been obvious. Thus, instant tablet and method of breaking the tablet would have been obvious over the claims of '935 patent.

8. 7329418 patent claims are substantially similar to the patented claims of 7318935 and hence for the reasons explained in the preceding paragraph, instant claims are obvious over the claims of '418 patent.

9. 7713547 patent claims

THE FOLLOWING CLAIMS 10.

1. A method of administering a partial dose of a drug contained in a pharmaceutical tablet, said method comprising: 10
- (a) providing a tablet comprising at least a first and second segment which are compositionally distinct, said first segment containing a drug in a pharmacologically effective amount and said second segment: 15
- (i) contains no detectable drug or the same drug which is in said first segment in a pharmacologically ineffective amount and also includes a third segment having the same drug that is present in said first segment; and 20
- (ii) said second segment is interposed between said first and third segments;
- (b) breaking said tablet through the second segment without damage to the first or third segments to form two or more tablettes; and 25
- (c) orally administering to a patient at least one tablette formed by said breaking of the tablet.

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11. Further, the above tablet contains a score or indicia such as perforation, printed material or gelatin mark in one or more segments. The drugs present in the first and second segments are compatible but may be same or different. While the above patent do not state that the inner segment is of a different color than the first and second segments, it would have been obvious for a skilled artisan at the time of the instant invention was made to employ different colored segments in the tablet of said patent such that the different segments are easily identified and the breaking of the tablet through the score present in a middle colored segment would have been obvious. Thus, instant tablet and method of breaking the tablet would have been obvious over the claims of '547 patent.

12. Patent 7622137 claims

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## THE INVENTION CLAIMED IS:

1. A dosage form comprising a capsule or sachet containing  
a divisible dose tablet, said tablet comprising a plurality of  
compressed segments, said tablet having a top and a bottom,  
and having a height that exceeds the width of said tablet, said  
height being measured vertically from the top to the bottom of  
said tablet while it is in a tablet die in which it is fully  
compressed, after said compression has been completed; and  
said width being measured as the greatest horizontal dimen-  
sion of the tablet at a location halfway between said top and  
said bottom of said tablet, except that when the horizontal  
cross-section of said tablet is substantially rectangular, the  
width is defined by locating the two shorter sides of the  
perimeter of said horizontal cross-section, and measuring the  
length of a line that is at right angle to said shorter sides, said  
segments being compressed in a tablet die to form a taller-  
than-wide segmented tablet in said tablet die, wherein at least  
two segments are active segments comprising a composition  
containing one or more active pharmaceutical ingredient, and  
at least one of said plurality of compressed segments is an  
inactive segment located between said at least two active  
segments, said inactive segment forming a breaking region  
for dividing said tablet there through to provide at least two  
tablettes each comprising a compressed active segment and a  
portion of the compressed inactive segment.

13.

14. While the above patent fails to teach the claimed score or an indicia and also lacks a colored inner segment, the tablets of the above patent have the same purpose i.e., divisible so as to distribute partial dosages. Accordingly, it would have been obvious for a skilled artisan at the time of the instant invention was made to employ different colored segments in the tablet of said patent such that the different segments are easily identified and the breaking of the tablet through the score present in a middle colored



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segment would have been obvious. Further, employing a suitable means such as score or mark or line to divide the tablet evenly such that the tablet is not broken unevenly and the active agents on either side of the breakable segment are not lost in the process. Thus, instant tablet and method of breaking the tablet would have been obvious over the claims of '137 patent.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0132850 to Bartholomaeus et al (Bartholomaeus), and further in view of US 5756124 to Patel et al and 6,375,956 to Hermelin et al.

Bartholomaeus teach a multilayered tablet (three or five or upto seven layers) containing two different actives (tramadol and diclofenac), each in a separate layer and separating layer between the active layers. This separating layer is clearly provided to ensure complete separation of the two active layers and to minimize interaction between the two different actives or the compositions comprising those actives, which may be pharmaceutically incompatible with one another. Bartholomaeus teaches incorporating an immediate release substance, for an initial dose of pain relieving active agent (0013). Bartholomaeus teaches that the tablet may contain upto five or seven layers (0009). Applicants state that the inactive segment of the instant invention

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provides an advantage of separating the actives (page 10). In this regard, Bartholomaeus teaches separation of the active agents by the addition of an inactive barrier layer and thus meets instant invention.

For claimed score mark, Bartholomaeus further teaches that the tablet provides at least one score mark that enables the dose being administered into two halves, so as to match to the individual requirements of the patient (0030-0031). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include a score mark in the middle segment of Bartholomaeus so as to achieve two equal halves of a tablet containing different active agents. Bartholomaeus does not state if the score is vertically oriented. However the prior art is also silent if the score is horizontal and therefore it is the position of the examiner that the mark is not horizontally placed in Bartholomaeus. Further, Bartholomaeus suggests that the score may be placed such that the tablet may be halved. Accordingly, choosing the size and orientation of the score so as to break the tablet exactly into halves would have been within the scope of a skilled artisan.

Bartholomaeus fails to teach the claimed indicia and also lacks the color in the inner segment. However, the teachings of Patel and Hermelin are relied upon for the same. Patel teaches breakable multiscored tablets wherein the tablets can be divided in to plurality of predetermined dosages and the dosages are separated by score marks. Figs. 1 and 2 of Patel show the score marks as well as indicia on the tablets which indicate the dosage of the tablet fraction. Hermelin teaches strip pack containing drugs that require complex dosage regiment for simultaneous administration of drugs

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(abstract) based on individual requirement. The blister packs of Hermelin contains plurality of predetermined dosages of drugs, wherein a day indicia is provided with each dosage (col. 6), for dispensing combinations of drugs (col. 8). Hermelin also suggests color coding the different drugs such that the drugs can be taken at different times of the day (col. 16, l 35+). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ not only score (of Bartholomaeus) for breaking the tablet accurately, but also include indicia on the tablets for instance the type of drug included or color code so as to indicate the inert or drug containing segments in the tablet of Bartholomaeus such that the tablet can be broken for appropriate drug based on the information printed or the color code, from either top or bottom segment of the tablet, without losing the active agent during breakage and dispensing. Further, a skilled artisan would have recognized that employing more than one score for easy breakage of the tablet as needed is routine in the art from the teachings of Patel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/  
Primary Examiner, Art Unit 1611